

## REMARKS

Claims 1-20 were pending at the time of the Office action. Claims 4, 7-12, 15, 16, and 18-20 have been withdrawn from consideration. Claims 1-3, 5-6, 13, 14, and 17 stand rejected under 35 U.S.C. § 101. Claims 1-3, 5-6, 13, 14, and 17 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 1-3, 5-6, 13, 14, and 17 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 1-3, 5-6, 13, 14, and 17 stand rejected under 35 U.S.C. § 102. Applicants address each of these rejections as follows.

### Claim Amendments

Claim 1 has been amended to feature an isolated protein, wherein the protein is an active mature protein and a) has the sequence of SEQ ID NO: 1 (SAP-2), b) has allelic modifications of SEQ ID NO: 1, whereby at least one amino acid of the amino acid sequence is substituted, deleted, or inserted, without in this case significantly affecting the activity of the active protein, or c) has post-translational modifications of SEQ ID NO: 1 that do not significantly affect the activity of the active protein, and wherein the activity of the active protein is antimicrobial or antibiotic activity. Support for this amendment is found, for example, on page 31, Example 1, of the English language translation of the specification filed on January 22, 2002, and on page 3, lines 22-26, through page 4, lines 1-14, of the English language specification. Applicants note that elements previously featured in canceled claim 2 have been incorporated into claim 1. Claim 17 has been amended to feature a method of treating or preventing infections caused by microorganisms in a subject in need thereof by administering to the subject one or more of the proteins described in claim 1. Support for this amendment is found, for example, on page 26, lines 1-10, of the English language specification.

The present amendments were made solely to expedite prosecution, and Applicants reserve the right to pursue any canceled subject matter in this or in a continuing

application. No new matter has been added.

### Objections to the Claims

Claim 1 has been objected to for a minor informality. Applicants submit that the objection has been overcome by the present claim amendment.

### Rejections under 35 U.S.C. § 101

Claims 1-3, 5-6, 13, 14, and 17 stand rejected under 35 U.S.C. § 101 as failing to sufficiently distinguish over cells that exist naturally because the claims do not particularly point out non-naturally occurring differences between the claimed product and the product of nature. To expedite prosecution, claim 1 has been amended to feature an “isolated” protein, as suggested by the Examiner.

In addition, claim 17 stands rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in the improper definition of a process. Applicants have amended claim 17 to feature a method of treating or preventing infections caused by microorganisms in a subject in need thereof, wherein the method includes administering to the subject one or more of the proteins described in claim 1.

The rejections of claims 1-3, 5-6, 13, 14, and 17 under 35 U.S.C. § 101 should be withdrawn.

### Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-3, 5-6, 13, 14, and 17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner states (page 4) that “the language protein/peptide is unclear as to whether the applicant is claiming a mature protein or peptide (protein fragment).” To clarify this language, Applicants have amended claim 1 to feature an isolated “protein,” wherein the protein is an active mature protein.

Applicants note, however, that the term “protein” comprises all lengths of amino acid sequences, including peptides (see, e.g., page 29, lines 17-20, of the English language specification). Claim 1 has been further amended to include sections a), b), and c), as suggested by the Examiner. Additionally, the Examiner states (page 4) that claim 1 “is vague in reciting ‘activity of active protein.’” Applicants have amended claim 1 to recite that the activity of the active protein is antimicrobial or antibiotic activity (a feature of canceled claim 2).

Turning to claim 17, the Examiner states (page 4) that the claim does not set forth any steps involved in a method or process. Applicants have amended claim 17 to feature a method of treating or preventing infections caused by microorganisms in a subject in need thereof, wherein the method includes administering to the subject one or more of the proteins described in claim 1. Accordingly, the rejection of claims 1-3, 5-6, 13, 14, and 17 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

#### Rejections under 35 U.S.C. § 112, first paragraph

##### *Written Description*

Claims 1-3, 5-6, 13, 14, and 17 stand further rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner states (page 5) that the specification “fails to describe a ‘representative number’ of [variants of SEQ ID NO: 1].” To expedite prosecution, Applicants have amended claim 1 to feature an isolated protein, wherein the protein is an active mature protein and a) has the sequence of SEQ ID NO: 1 (SAP-2), b) has allelic modifications of SEQ ID NO: 1, whereby at least one amino acid of the amino acid sequence is substituted, deleted, or inserted, without in this case significantly affecting the activity of the active protein, or c) has post-translational modifications of SEQ ID NO: 1 that do not significantly affect the activity of the active protein, and wherein the activity of the active protein is antimicrobial or antibiotic activity. Applicants submit that claim 1, as amended, satisfies the written description

requirement, as the proteins covered by claim 1 are required to possess antimicrobial or antibiotic activity. Further to this point, the specification recites, with respect to variants, that “the function of the altered protein must be compared with the function of the protein according to the invention... [and] the methods that are used for this purpose are indicated in the example” (see, e.g., page 18, lines 25-27, through page 19, lines 1-3, of the English language specification). Thus, one skilled in the art would reasonably be able to identify proteins of the invention with antimicrobial or antibiotic activity.

### *Enablement*

Claims 1-3, 5-6, 13, 14, and 17 also stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner states (page 8) that “the specification... does not reasonably provide enablement for any variant protein [of] SEQ ID NO: 1, a pharmaceutical composition comprising said variants of SEQ ID NO: 1, and a method for treating or preventing infections comprising said SEQ ID NO: 1 or variants of SEQ ID NO: 1.” As described above, claim 1 has been amended to feature proteins that demonstrate antimicrobial or antibiotic activity. Applicants refer to Example 3 (page 36 of the English language specification), wherein the routine determination of antimicrobial activity of a protein of the invention is described. As such, Applicants request reconsideration and withdrawal of the rejection of claims 1-3, 5-6, 13, 14, and 17 under 35 U.S.C. § 112, first paragraph.

### Rejections under 35 U.S.C. § 102

Claims 1-3, 5-6, 13, 14, and 17 stand rejected under 35 U.S.C. § 102(a) as being anticipated by European Patent Application No. 0 943 679, published on September 22, 1999. Applicants note that the present application has a priority date of February 1, 1999, corresponding to the filing of German Patent Application No. 199 05 128.3, which predates the publication date of the cited art. Applicants submit an English language

translation of German Patent Application No. 199 05 128.3 and a signed statement that the translation of the application is accurate. As will be appreciated by the Office, the priority document fully supports the claims presently under consideration. Accordingly, the rejection of claims 1-3, 5-6, 13, 14, and 17 under 35 U.S.C. § 102 should be withdrawn.

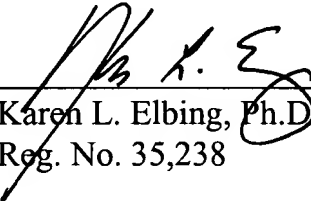
### CONCLUSION

Applicants submit that the application is in condition for allowance, and this action is hereby respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including January 12, 2008, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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